REMARKS

I. General

Claims 1-34 were pending in the present application. Claims 15-34 were withdrawn from consideration, and claims 1-14 were rejected in the current Office Action (mailed October 2, 2003). The outstanding issues in the current Office Action are:

- The abstract of the disclosure is objected to;

- Claims 1-14 are rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter;

- Claims 1-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

- Claims 1, 3, 8-9, and 11-14 are rejected under 35 U.S.C. § 102(a) as being anticipated by an article titled "Oscillating Search Algorithms for Feature Selection" by Pudil et al. (hereinafter "*Pudil*"); and

- Claims 1, 3, 8-9, and 12-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by an article titled "Floating search methods in feature selection" by Pudil et al. in Pattern Recog. Lett. (1994), vol. 15, pp. 1119-1125 (hereinafter "*Pudil_2*").

In response, Applicant respectfully traverses the outstanding claim rejections, and requests reconsideration and withdrawal thereof in light of the amendments and remarks presented herein.

II. Amendments

A. In the Specification

The abstract of the disclosure is amended herein to correct the first sentence thereof so that it is not a sentence fragment. This amendment is made solely to overcome the outstanding objection to the abstract and is not intended to narrow the scope of the disclosure

or claims in any way.

B. In the Claims

Claims 2-3, 7, 9, 11, and 14 are amended, claims 4-6, 8, and 15-34 are deleted without prejudice, and new claims 35-70 are added herein. No new matter is presented by these amendments and newly added claims.

III. Objection to the Abstract

In view of the amendment to the abstract presented herein, Applicant respectfully requests withdrawal of the outstanding objection to the abstract.

IV. Claim Rejections under 35 U.S.C. § 101

Claims 1-14 are rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicant respectfully submits that independent claim 1 is directed to proper statutory subject matter under 35 U.S.C. § 101, as discussed further below.

35 U.S.C. § 101 provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title" (emphasis added). M.P.E.P. § 2106.IV.A. explains:

> As cast, 35 U.S.C. 101 defines four categories of inventions that Congress deemed to be the appropriate subject matter of a patent; namely, processes, machines, manufactures and compositions of matter. The latter three categories define "things" while the first category defines "actions" .... See 35 U.S.C. 100(b) ("The term 'process' means process, art, or method, and includes a new use of a known process, machine manufacture, composition of matter, or material.").

M.P.E.P. § 2106.IV.A. further explains that the "subject matter courts have found to be outside the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena" (emphasis added). "These three exclusions recognize that subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomena is not patentable." M.P.E.P. § 2106.IV.A. (emphasis in original).

Independent claim 1 is directed to a "method", which as described above is one of the four statutory categories found in 35 U.S.C. § 101 (i.e., processes). Further, claim 1 recites subject matter that is a practical application or use for the method. More specifically, claim 1 recites a "method for determining a predictor set of features associated with a target". As described in the specification of the present application, determining such a predictor set of features for predicting a target has much application in, as examples, using such predictor set of features for identifying a gene of interest in a sample or disease identification. *See e.g.,* pages 1-3 and page 7, line 18- page 8, line 18 of the present application. The present application defines the term "feature" as "expression levels or biological data of a defined gene, protein, or other biological function or component under consideration and over a prescribed number of experiments." Page 5, lines 24-26 of present application. Again, the present application describes that determining a predictor set of such features associated with a target has a desirable application in that the determined predictor set can be used for identifying a target (e.g., a gene of interest, etc.). Also, newly added dependent claim 35 specifically recites, for example, "determining a best predictor set of k number of features ... and using the determined best predictor set of k features for predicting said target." Thus, Applicant respectfully submits that the recited method of claim 1 satisfies the "practical application or use" criteria because it provides an efficient and accurate technique for determining a predictor set of features associated with a target for use in predicting the target.

Additionally, as noted in the current Office Action (at page 3 thereof), the specification of the present application teaches that the claimed method may be a computer-implemented one. For example, claim 14, which depends from independent claim 1, recites "wherein said steps of selecting and adding are performed by a processor-based device using a first algorithm, and wherein said checking step is performed by a separate algorithm", and newly added claim 51, which depends indirectly from independent claim 1, recites "performing at least said adding, checking, removing, and determining steps with a processor-based device."

"To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan ..., or (B) be limited to a practical application within the technological arts".

M.P.E.P. § 2106.IV.B.2(b). With regard to element (A) above (i.e., physical transformation outside the computer), various "safe harbors" have been identified, which are deemed to satisfy this element (A) and thus be considered as directed to proper statutory subject matter. One such safe harbor is a process in which data representing physical objects or activities are manipulated (e.g., measurements of such physical objects or activities are transformed into computer data). *See* M.P.E.P. § 2106.IV.B.2(b)(i). One example of this type of "safe harbor" is identified in M.P.E.P. § 2106.IV.B.2(b)(i) as follows:

> A method of using a computer processor to analyze electrical signals and data representative of human cardiac activity by converting the signals to time segments, applying the time segments in reverse order to a high pass filter means, using the computer processor to determine the amplitude of the high pass filter's output, and using the computer processor to compare the value to a predetermined value. In this example the data is an intangible representation of physical activity, i.e., human cardiac activity. The transformation occurs when heart activity is measured and an electrical signal is produced. This process has real world value in predicting vulnerability to ventricular tachycardia immediately after a heart attack.

Similarly, claim 1 is directed to a statutory process in determining a predictor set of features associated with a target. In performing this process in a computer implementation, information regarding the features associated with the target are transformed into computer data. For instance, information regarding features associated with such a target as protein, gene, or immunological information (*see e.g.,* definition of "target" at page 5, line 32 – page 6, line 4 of the present application) is transformed into computer data for performing the steps performed by a computer, such as the adding, checking, removing, and determining steps (as recited in claim 51). Thus, a transformation occurs when the features are measured and transformed to computer data (e.g., electrical signals). The process has real-world value in predicting a target, such as genes in a sample, using the determined predictor set of features.

The current Office Action further asserts that claims 1-14 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility. *See* page 4 of Office Action. Applicant respectfully disagrees. As M.P.E.P. § 2107.02.I. provides "regardless of the category of invention that is claimed (e.g., product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112". *Citing In re Gottlieb,* 328 F.2d 1016, 1019, 140 USPQ 665, 668 (CCPA 1964) ("Having found that the antibiotic is useful for some purpose, it becomes unnecessary

to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful."). "Thus, if applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established." M.P.E.P. § 2107.02.I.

As explained by M.P.E.P. § 2107.02.II.A, an assertion of utility in the specification is sufficient for satisfying the utility requirement. For example, "a disclosure that identifies a particular biological activity of a compound and explains how that activity can be utilized in a particular therapeutic application of the compound does contain an assertion of specific and substantial utility for the invention." M.P.E.P. § 2107.02.II.A. In the present application, claim 1 is directed to a "method for determining a predictor set of features associated with a target". The specification of the present application identifies at least one utility for determining such a predictor set of features. For instance, determining such a predictor set of features for predicting a target has much utility in using such predictor set of features for identifying a gene of interest in a sample or disease identification, as examples. *See e.g.,* pages 1-3 and page 7, line 18- page 8, line 18 of the present application.

Accordingly, Applicant respectfully submits that the utility requirement is satisfied by the present application. "In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101." M.P.E.P. § 2107.02.III.A. Further, as described above, at least one utility of determining a predictor set of features associated with a target involves pharmacological or therapeutic utility (e.g., using the predictor set for identifying a set of genes that can predict a target such as lukemia, *see* page 18, lines 18-31 of the present application). M.P.E.P. § 2107.03 notes that the "Federal Court have consistently reversed rejections by the Office asserting a lack of utility for inventions claiming a pharmacological or therapeutic utility where an applicant has provided evidence that reasonably supports such a utility" and thus "Office personnel should be particularly careful in their review of evidence provided in support of an asserted therapeutic or pharmacological utility."

In view of the above, Applicant respectfully submits that independent claim 1 is directed to statutory subject matter having sufficient utility in compliance with 35 U.S.C. § 101 (i.e., directed to a proper "process"). Accordingly, dependent claims 2-3, 7, 7-13, and 35-52, which each depend either directly or indirectly from independent claim 1, are also believed to be directed to proper statutory subject matter under 35 U.S.C. § 101. However,

Applicant respectfully reminds the Examiner that M.P.E.P. § 2106.IV.B. provides that in a case in which the invention as set forth in the written description is statutory but the claims define subject matter that is not, "Office personnel should reject the claims drawn to nonstatutory subject matter under 35 U.S.C. 101, but identify the features of the invention that would render the claimed subject matter statutory if recited in the claim" (emphasis added). Thus, Applicant respectfully requests that if the Examiner maintains that claim 1 is not directed to proper statutory subject matter the Examiner identify the features of the invention that would render the claimed subject matter statutory if recited in the claim. Otherwise, Applicant respectfully requests that this rejection of claims 1-14 under 35 U.S.C. § 101 be withdrawn. Additionally, Applicant reminds the Examiner that each claim is to be judged under 35 U.S.C. § 101, and thus if the rejection is maintained for independent claim 1, Applicant requests that the Examiner further evaluate each claim depending either directly or indirectly from claim 1 to determine whether each of those claims is considered proper under 35 U.S.C. § 101.

V. Claim Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to independent claim 1, the current Office Action asserts that the preamble recites a method of determining a predictor set of features, while the claim does not recite any step that may be interpreted to be a "determining" step, and thus the claim is indefinite. Page 5 of current Office Action. However, Applicant respectfully submits that the claim is sufficiently definite under 35 U.S.C. § 112, second paragraph because it clearly recites steps that are performed in determining a predictor set of features associated with a target. While the body of the claim does not specifically recite the word "determining," the body does recite steps that are used in performing the "determining a predictor set" as recited in the preamble. In other words the process of performing the "determining" recited in the preamble comprises the steps recited in the body of the claim. Further, Applicant respectfully submits that the recited "checking" step (c) may be reasonably interpreted as a determining step in that it "determines" whether all of the features are repeated. Accordingly, Applicant respectfully submits that independent claim 1 is sufficiently definite as to comply with 35

U.S.C. § 112, second paragraph.

The amendments presented herein for claims 2, 3, 7, 11, and 14 are believed to overcome the outstanding rejections of those respective claims under 35 U.S.C. § 112, second paragraph. That is, claims 2, 3, 7, 11, and 14, as amended herein, are respectfully submitted to be sufficiently definite as to comply with 35 U.S.C. § 112, second paragraph.

With regard to claim 12, the current Office Action asserts that there is no antecedent basis for "the target" recited in this claim. Applicant respectfully disagrees. Claim 12 depends from independent claim 1, which, as amended herein, recites, in part, "determining a predictor set of features associated with a target" (emphasis added). Thus, claim 1 provides sufficient antecedent basis for the term "the target" recited in dependent claim 12.

In view of the above, Applicant respectfully requests withdrawal of the outstanding claim rejections under 35 U.S.C. § 112, second paragraph.

VI. Claim Rejections under 35 U.S.C. § 102(a) over *Pudil*

Claims 1, 3, 8-9, and 11-14 are rejected under 35 U.S.C. § 102(a) as being anticipated by the article titled "Oscillating Search Algorithms for Feature Selection" by Pudil et al. (referenced herein as "*Pudil*"). As described above, claim 8 is deleted without prejudice herein, and thus the rejection of that claim is now moot. With regard to claims 1, 3, 9, and 11-14, Applicant respectfully submits that *Pudil* fails to anticipate these claims, as discussed further below.

To anticipate a claim under 35 U.S.C. § 102, a single reference must teach every element of the claim, *see* M.P.E.P. § 2131. As discussed further below, *Pudil* does not teach every element of claims 1, 3, 9, and 11-14, and therefore fails to anticipate such claims under § 102(a).

More specifically, independent claim 1 recites, *inter alia*, "checking to see if all of said features are repeated". *Pudil* fails to teach at least this element of claim 1. Rather, *Pudil* teaches an oscillating search algorithm having steps 1-5 as described on page 407 thereof and following the operational flow of FIGURE 2 shown on page 408 thereof. The oscillating search algorithm taught by *Pudil* does not check to see if all of the features of a predictor set

are repeated, as recited by claim 1. Accordingly, *Pudil* fails to teach at least this element of claim 1.

In view of the above, independent claim 1 is not anticipated by *Pudil* under 35 U.S.C. § 102(a). As such, Applicant respectfully requests withdrawal of this rejection. Further, each of dependent claims 3, 9, and 11-14 depend either directly or indirectly from independent claim 1, and thus inherit all limitations of independent claim 1. It is respectfully submitted that dependent claims 3, 9, and 11-14 are allowable not only because of their dependency from independent claim 1 for the reasons discussed above, but also in view of their novel claim features (which both narrow the scope of the particular claims and compel a broader interpretation of the respective base claim from which they depend).

VII. Claim Rejections under 35 U.S.C. § 102(a) over *Pudil_2*

Claims 1, 3, 8-9, and 12-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by the article titled "Floating search methods in feature selection" by Pudil et al. (referenced herein as "*Pudil_2*"). As described above, claim 8 is deleted without prejudice herein, and thus the rejection of that claim is now moot. With regard to claims 1, 3, 9, and 12-14, Applicant respectfully submits that *Pudil_2* fails to anticipate these claims, as discussed further below.

To anticipate a claim under 35 U.S.C. § 102, a single reference must teach every element of the claim, *see* M.P.E.P. § 2131. As discussed further below, *Pudil_2* does not teach every element of the rejected claims, and therefore fails to anticipate such claims under § 102(b).

More specifically, independent claim 1 recites, *inter alia*, "checking to see if all of said features are repeated". *Pudil_2* fails to teach at least this element of claim 1. *Pudil_2* teaches a floating search method. For instance, the abstract of *Pudil_2* explains that "[s]equential search methods characterized by a dynamically changing number of features included or eliminated at each step, henceforth 'floating' methods, are presented." *Pudil_2* provides at page 1119 thereof:

With the feature set search algorithms discussed in this paper the best feature set is constructed by adding to and/or removing from the current feature set, a small number of measurements at a time until the required feature set, X_d, of cardinality d is obtained. More specifically, to form the best set of d features, the starting point of the search can be either an empty set, $X0$, which is then successively built up or the starting point can be the complete set of measurements, Y, in which superfluous measurements are successively eliminated. The former approach is referred to as the "bottom up" search while the latter is known as the "top down" method.

Pudil_2 further describes the operational flow of the proposed floating search method in section 2 thereof (*see* pages 1120-1123 of *Pudil_2*). However, the floating search algorithm taught by *Pudil_2* does not check to see if all of the features of a predictor set are repeated, as recited by claim 1. Accordingly, *Pudil_2* fails to teach at least this element of claim 1.

In view of the above, independent claim 1 is not anticipated by *Pudil_2* under 35 U.S.C. § 102(b). As such, Applicant respectfully requests withdrawal of this rejection. Further, each of dependent claims 3, 9, and 12-14 depend either directly or indirectly from independent claim 1, and thus inherit all limitations of independent claim 1. It is respectfully submitted that dependent claims 3, 9, and 12-14 are allowable not only because of their dependency from independent claim 1 for the reasons discussed above, but also in view of their novel claim features (which both narrow the scope of the particular claims and compel a broader interpretation of the respective base claim from which they depend).

VIII. Newly Added Claims 35-70

Newly added claims 35-70 are also believed to be allowable over the applied art of record. For instance, claims each 35-52 depend either directly or indirectly from independent claim 1, and thus inherit all limitations of independent claim 1. As discussed above, independent claim 1 is believed to be allowable over the applied art of record. It is respectfully submitted that dependent claims 35-52 are allowable not only because of their dependency from independent claim 1 for the reasons discussed above, but also in view of their novel claim features (which both narrow the scope of the particular claims and compel a broader interpretation of the respective base claim from which they depend). For example,

dependent claim 39, recites "wherein said checking step comprises checking to see if all of said k features of said predictor set have been repeated k times in a row." Neither *Pudil* nor *Pudil_2* teaches checking to see if k features of a predictor set have been repeated k times in a row.

Independent claim 53 recites, *inter alia*, "determining whether the features of the predictor set have appeared k consecutive times". Both *Pudil* and *Pudil_2* fail to teach at least this element of claim 53. As such claim 53 is believed to be of allowable merit. Claims 54-57 each depend from independent claim 53, and are believed to be allowable not only because of their dependency from independent claim 53, but also in view of their novel claim features (which both narrow the scope of the particular claims and compel a broader interpretation of the respective base claim from which they depend).

Independent claim 58 recites, *inter alia*, "(e) determining whether the counter equals k; (f) if the counter equals k, then determining that the first predictor set is a best predictor set of k features for predicting said target; (g) if the counter does not equal k, then removing a feature from the other end of the list of features that forms the first predictor and adding to the one end of the list a second complement feature to form a second predictor set and proceed to step (h)". Both *Pudil* and *Pudil_2* fail to teach at least these elements of claim 58. For instance, neither *Pudil* nor *Pudil_2* teach determining whether the recited counter equals k (i.e., the number of features in the predictor set). Further, neither *Pudil* nor *Pudil_2* teach determining the predictor set as a best predictor set when the counter equals k, nor does *Pudil* or *Pudil_2* teach removing a feature from the list of features and adding a complement feature to the list if the counter does not equal k. As such independent claim 58 is believed to be of allowable merit. Claim 59 depends from independent claim 58, and is believed to be allowable not only because of its dependency from independent claim 58, but also in view of its novel claim features.

Independent claim 60 recites, *inter alia*, "iteratively performing (i) determining whether the features of the predictor set have been encountered k consecutive times, and (ii) if the features of the predictor set have not been encountered k consecutive times, then removing a feature from the ordered subset and adding a complement feature to the ordered subset". Both *Pudil* and *Pudil_2* fail to teach at least these elements of claim 60. For instance, neither *Pudil* nor *Pudil_2* teach determining whether the features of the predictor set

have been encountered *k* consecutive times. As such, independent claim 60 is believed to be of allowable merit. Claims 61-62 each depend either directly or indirectly from independent claim 60, and are believed to be allowable not only because of their dependency from independent claim 60, but also in view of their novel claim features (which both narrow the scope of the particular claims and compel a broader interpretation of the respective base claim from which they depend).

Claim 63 recites, *inter alia*, "the processor-based device iteratively performing (i) determining whether the features appearing on the list have repeatedly appeared on the list *k* consecutive iterations, and (ii) if the features have not appeared on the list *k* consecutive iterations, then removing a feature from the other end of the list and adding a new complement feature to the one end of the list". Both *Pudil* and *Pudil_2* fail to teach at least these elements of claim 63. For instance, neither *Pudil* nor *Pudil_2* teach determining whether the features appearing on the list have repeatedly appeared on the list *k* consecutive iterations. As such independent claim 63 is believed to be of allowable merit. Claim 64 depends from independent claim 63, and is believed to be allowable not only because of its dependency from independent claim 63, but also in view of its novel claim features.

Independent claim 65 recites, *inter alia*, "(c) checking to see if all of said features of said predictor set have been repeated *k* times in a row". Both *Pudil* and *Pudil_2* fail to teach at least this element of claim 65. As such, independent claim 65 is believed to be of allowable merit. Claims 66-70 each depend either directly or indirectly from independent claim 65, and are believed to be allowable not only because of their dependency from independent claim 65, but also in view of their novel claim features (which both narrow the scope of the particular claims and compel a broader interpretation of the respective base claim from which they depend).

IX. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

The additional fee due with this Amendment for added claims and the one month extension are addressed in the transmittal. If any additional fee is due, please charge Deposit Account No. 50-1078, under Order No. 10004226-1 from which the undersigned is authorized to draw.

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Label No. EV 256030600US in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313.

Date of Deposit: January 14, 2004

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